IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group Art Unit 3732	:	PATENT APPLICATION
Examiner David A. Bonderer	:	
In re application of	:	PATELLA REPLACEMENT APPARATUS
ROBERT S. SUPINSKI	:	
Serial No. 10/007,812	:	
Filed November 8, 2001	:	

DECLARATION OF C. BRIAN McDANIEL
UNDER 37 C.F.R. § 1.131

I, C. Brian McDaniel, am the Manager of Custom Orthopaedics for Wright Medical Technology, a designer and manufacturer of orthopedic implants. Wright Medical Technologies was named Dow Corning Wright when I began my employment with the company in 1986. The company has also been named Wright Medical. Hereinafter, I will refer to the company as "Wright."

My first position with Wright was a lab technician responsible for the manufacture of custom implants. I attended college while working for Wright and received a bachelor of science degree in mechanical engineering from Memphis State University in 1990. Thereafter, I was promoted to process engineer and then design engineer. I became Manager of Custom Orthopaedics in July 1999.

I have continuously worked for Wright since 1987. I am familiar with the documents created and procedures followed by Wright in the design and manufacture of orthopedic implants. When a surgeon asks the company to make an implant, drawings are made by one of

our engineers. The implant is made and sent to the doctor within two to three weeks after the drawings are completed.

For many years Wright has made custom implants for Dr. Robert Supinski. Attached are drawings of a patella implant made in March or April, 1990, by Wright for Dr. Supinski in response to his request. At this time I personally do not know who designed the implant. As can be seen in the drawings, this implant has a first member fabricated from a biocompatible material. This first member is shown on the drawing labeled PALLECTOMY PATELLA - UHMW and has a rounded fixation surface for implantation in the patella region of a patient. The first member has a relatively flat surface opposite the rounded surface and an aperture in that flat surface. The patella replacement device also has a second member fabricated from a biocompatible joint articulating material. The second member is shown in the drawing labeled PALLECTOMY PATELLA - METAL. This member has a top rounded surface and an opposing surface having a projection which fits into the aperture in the first member to enable the first member to couple to the second member. The projection is best seen in the drawings labeled SECTION A-A and SECTION B-B. The second member allows articulation against the femoral area of the patient. A portion of the second member has a porous coating of hydroxapatite. This portion is shaded in the drawing and labeled "NOTE 3." There is an annular ring about the first member. Sixteen holes are provided in this ring. This annular ring is metal. A mating annular ring is provided on the first member. This mating ring also has sixteen holes.

In the implant shown in the drawings the first member is polyethylene and the second member is titanium and has a hydroxapatite coating. However, the materials could have been switched with the first member being polyethylene and the second member being porous metal. The porous metal allows biological fixation to the patella region of the patient.

The attached drawings were prepared by engineer Greg A. Gray in March, 1990. The patella replacement device shown in the drawings was made by Wright and sent to Dr. Supinski within three weeks of the drawing date, that is by April 13, 1990.

I know that Wright made additional patella replacement devices for Dr. Supinski that are identical or nearly identical to the implant shown in the attached drawings. Nine of these implants were made prior to June 1999. I prepared drawings for some if not all of these additional implants and supervised their manufacture. At that time I understood from Dr. Supinski that either member could be plastic as long as the other member was metal.

The information that Wright received from Dr. Supinski about the patella replacement devices was received in confidence. Wright has not disclosed the implants or the drawings for the implants to any third party. All implants that Wright has made for Dr. Supinski were shipped to Dr. Supinski or to his attention at a hospital selected by Dr. Supinski.

I declare that the foregoing is true and correct, that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: April 30, 2004

C. Brian McDaniel

READ YOUR DRAWING DO NOT SCALE
BREAK ALL SHARP EDGES .020 RAD MAX UNLESS OTHERWISE SPECIFIED

REV	ECR	REVISION	BY	DATE	CHK
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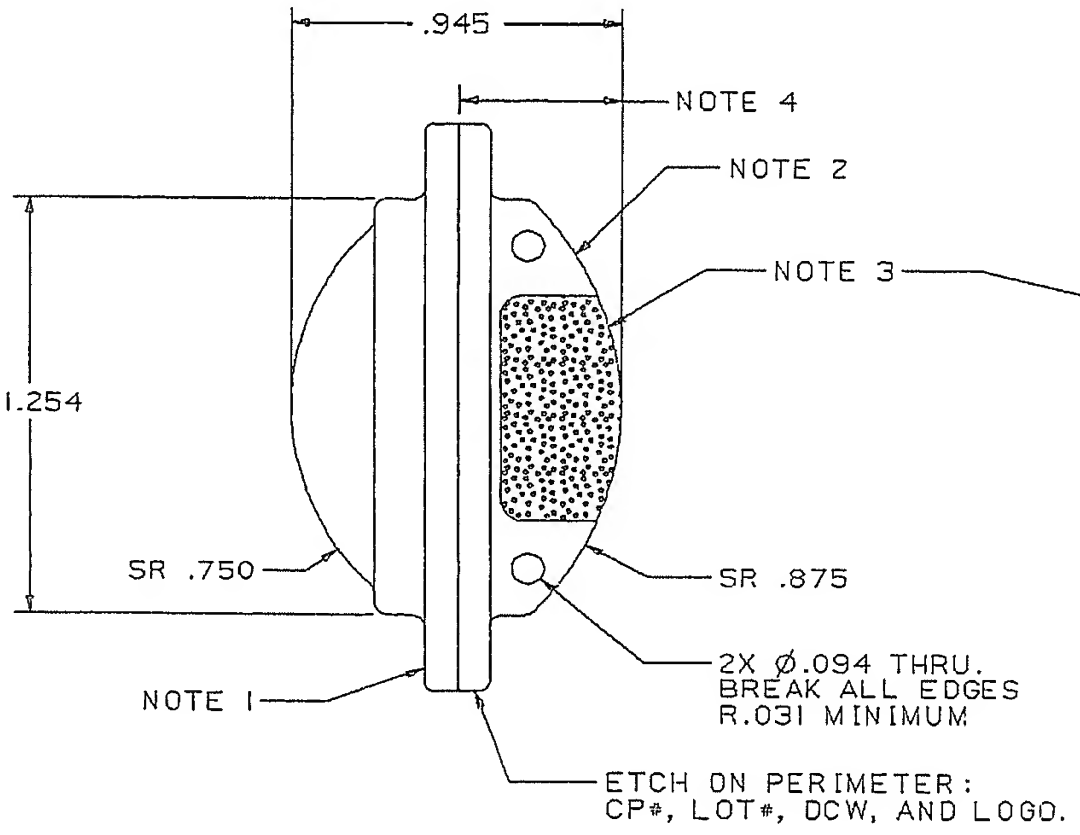
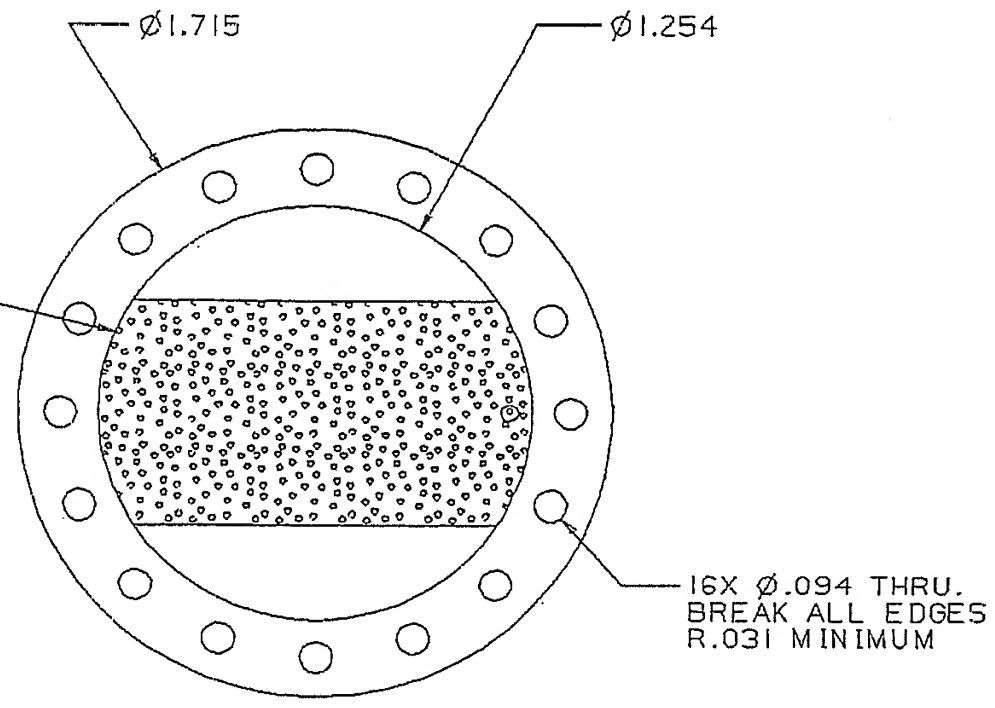
DWG. NO. C





NOTES:

1. UHMW POLYETHELENE COMPONENT
2. TI-6AL-4V COMPONENT
3. POROUS COATED AREA
4. H.A. COATED ON ALL SURFACES IN THIS REGION INCLUDING POROUS COATED REGION.

WORK ORDER_____

UNSPECIFIED TOLERANCES INCH .X ± .1 .XX ± .02 .XXX ± .005 ANGLE ± 1/2°	DOW CORNING WRIGHT P.O.BOX 100 ARLINGTON, TN 38002
DOW CORNING PROPRIETARY THIS MATERIAL IS CONSIDERED PROPRIETARY AND MUST NOT BE COPIED OR EXHIBITED EXCEPT WITH PERMISSION OF DOW CORNING WRIGHT'S RESEARCH & DEVELOPMENT DEPARTMENT AND MUST BE DESTROYED AFTER USE.	ASSEMBLY PATIENT: PHYSICIAN: R. SUPINSKI
	PART NAME PATELLECTOMY PATELLA - ASSEMBLY
MAT'L. TI-6AL-4V UHMWPE	DRAWN BY GAG · ENGINEERING CUSTOMS · MFGR. ENGR. .
	SCALE NTS · DATE 3-23-90 · DWG. NO. C · REV .

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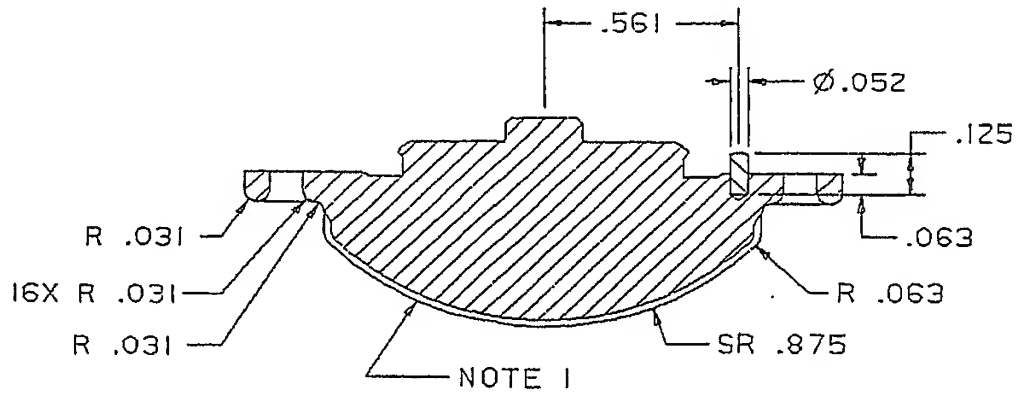
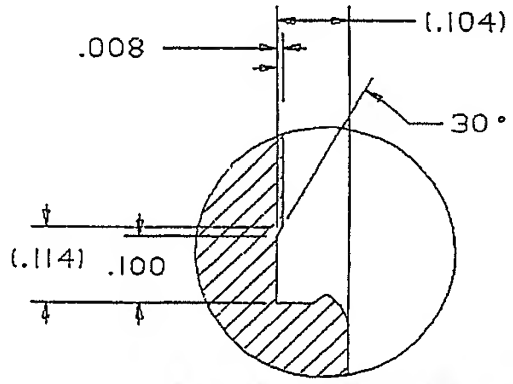
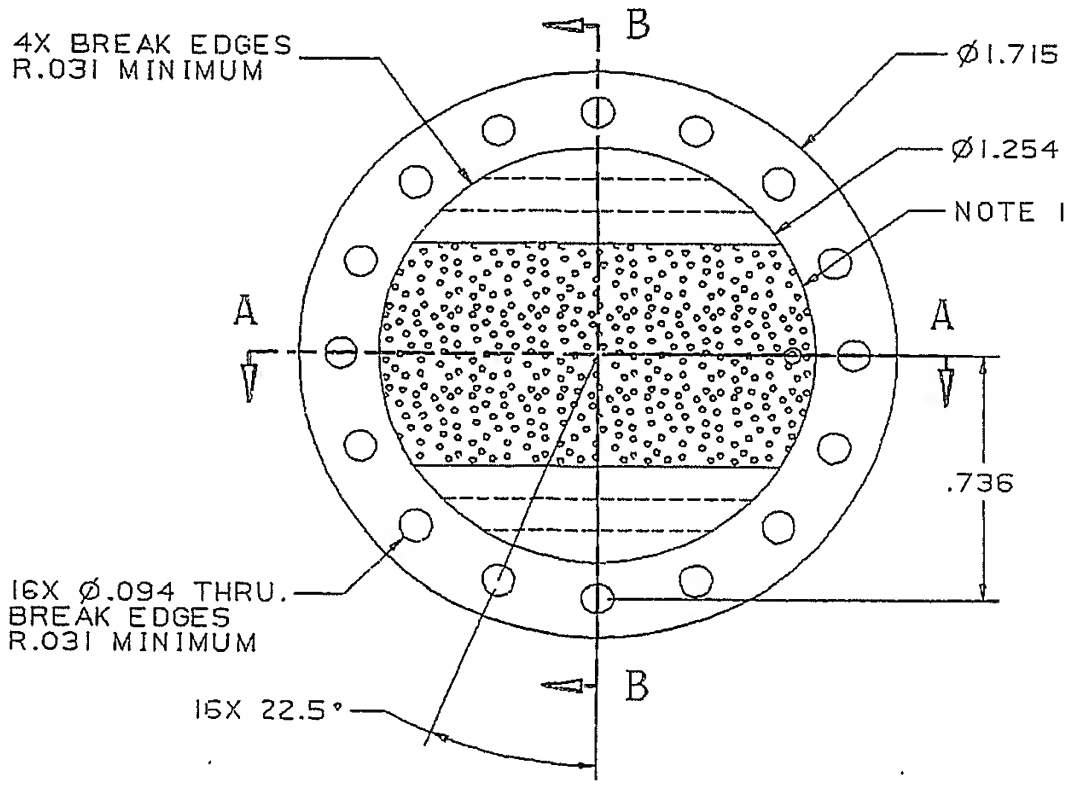
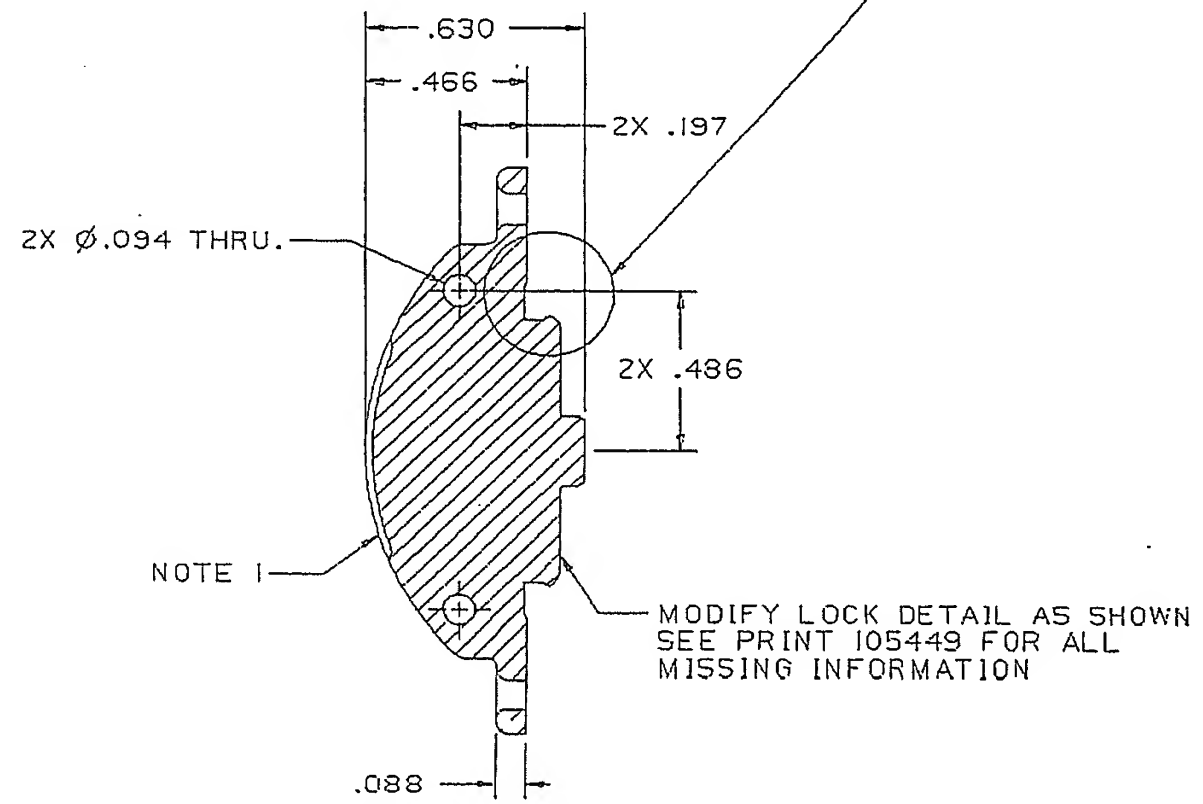


SECTION A-A



LOCK DETAIL





SECTION B-B

NOTES:

1. POROUS COAT PER QCP 7.0053 CLASS A, GRADE B IN THIS POCKETT
2. SEE POINT INFORMATION FOR POROUS COATING POCKET AND PROFILE DETAIL.
3. SOLUTION TREAT AND AGE PER QCP7.0052 OR PROPRIETARY PROCESS

WORK ORDER

UNSPECIFIED TOLERANCES
INCH
.X ± .1
.XX ± .02
.XXX ± .005
ANGLE ± 1/2°

MAT'L. TI-6AL-4V

DOW CORNING WRIGHT P.O.BOX 100 ARLINGTON, TN 38002

ASSEMBLY PATIENT:
PHYSICIAN: R. SUPINSKI

PART NAME
PATELLECTOMY PATELLA - METAL

DRAWN BY	ENGINEERING	MFGR. ENGR.
GAG	CUSTOMS	

SCALE NTS
DATE 3-23-90
DWG. NO. C
REV

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REV	ECR	REVISION	BY	DATE	CHK

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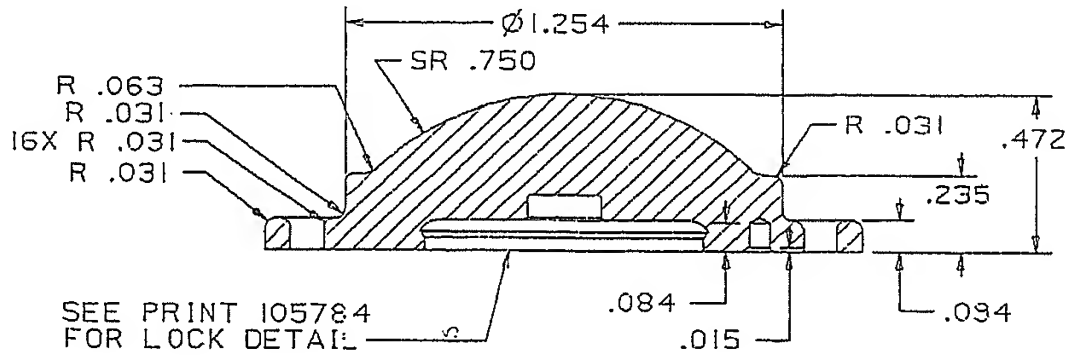
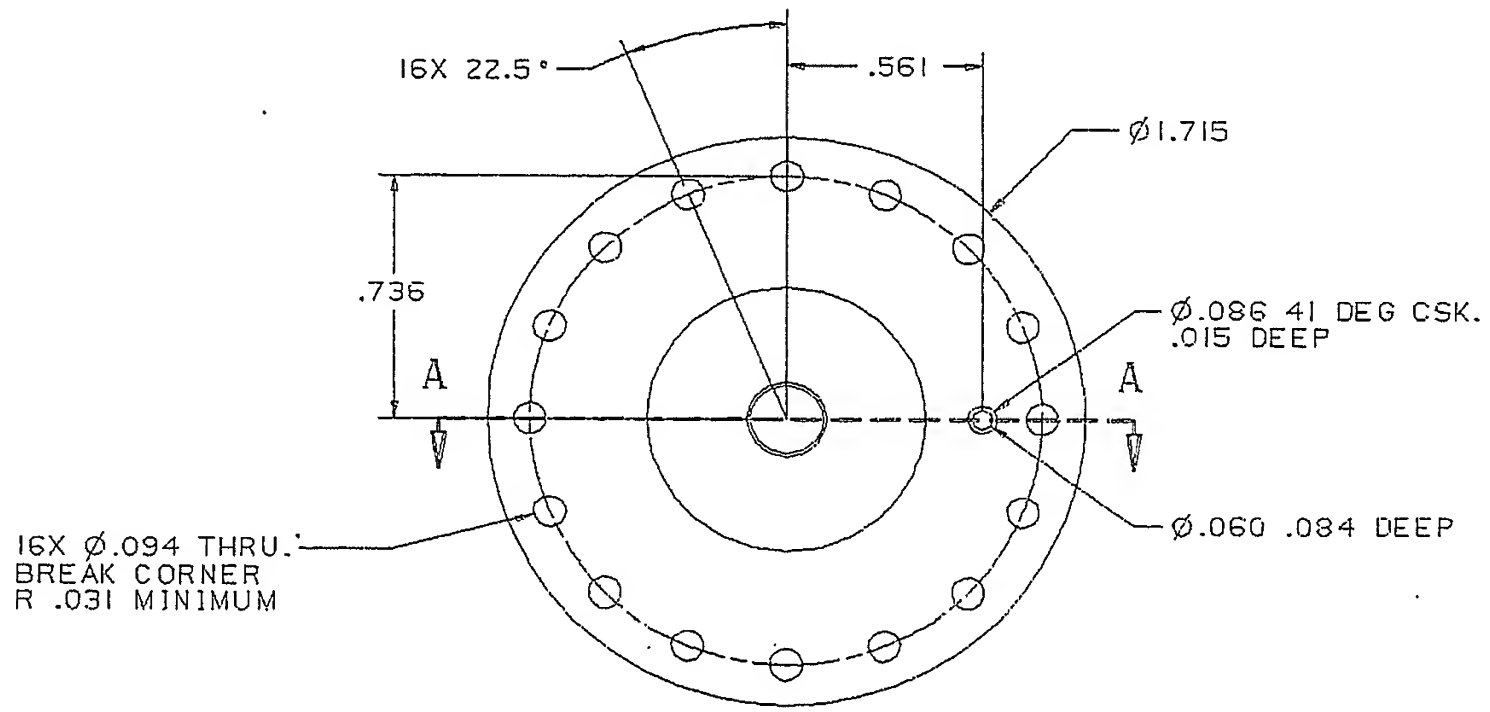


SECTION A-A



WORK ORDER_____

UNSPECIFIED TOLERANCES
INCH
.X ± .1
.XX ± .02
.XXX ± .005
ANGLE ± 1/2°

DOW CORNING PROPRIETARY

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MAT'L. UHMWPE

DOW CORNING WRIGHT P.O.BOX 100 ARLINGTON, TN 38002

ASSEMBLY PATIENT:
PHYSICIAN: R. SUPINSKI

PART NAME PATELLECTOMY PATELLA - UHMW

DRAWN BY	ENGINEERING	MFGR. ENGR.
GAG	CUSTOMS	

SCALE 3:1
DATE 3-24-90
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